Taj Pharmaceuticals Ltd.

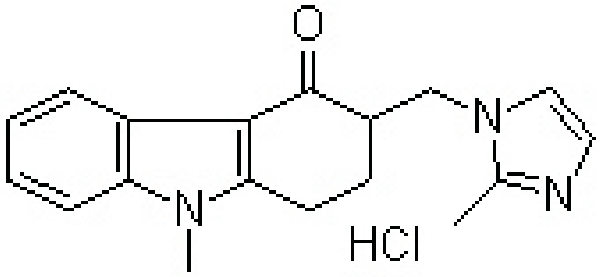
Ondansetron Hcl

CAS No. : 103639-04-9

Molecular Formula C18H19N3O.HCl
Molecular Weight 329.82
CAS Registry Number 103639-04-9 (99614-01-4)
ATC code A04AA01
PubChem 4595
DrugBank APRD00481
ChemSpider 4434

Chemical data

Formula C18H19N3O
Mol. mass 325.9 g/mol
SMILES eMolecules & PubChem



Pharmacokinetic data

Bioavailability ~60%
Protein binding 70%-76%
Metabolism Hepatic (CYP3A4, CYP1A2, CYP2D6)
Half life 5.7 hours
Excretion Renal

DOSAGE

The recommended adult oral dosage of Ondansetron Hcl is 24 mg given as three 8-mg tablets administered 30 minutes before the start of single-day highly emetogenic chemotherapy, including cisplatin ≥ 50 mg/m². Multiday, single-dose administration of a 24 mg dosage has not been studied.

Pediatric Use: There is no experience with the use of a 24 mg dosage in pediatric patients.

Geriatric Use: The dosage recommendation is the same as for the general population.

Prevention of Nausea and Vomiting Associated With Moderately Emetogenic Cancer Chemotherapy: The recommended adult oral dosage is one 8-mg Ondansetron Hcl Tablet or one 8-mg Ondansetron Hcl Tablet or 10 mL (2 teaspoonfuls equivalent to 8 mg of ondansetron) of Ondansetron Hcl Oral Solution given twice a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 8 hours after the first dose. One 8-mg Ondansetron Hcl Tablet or one 8-mg Ondansetron Hcl Tablet or 10 mL (2 teaspoonfuls equivalent to 8 mg of ondansetron) of Ondansetron Hcl Oral Solution should be administered twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

Pediatric Use: For pediatric patients 12 years of age and older, the dosage is the same as for adults. For pediatric patients 4 through 11 years of age, the dosage is one 4-mg Ondansetron Hcl Tablet or one 4-mg Ondansetron Hcl Tablet or 5 mL (1 teaspoonful equivalent to 4 mg of ondansetron) of Ondansetron Hcl Oral Solution given 3 times a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with subsequent doses 4 and 8 hours after the first dose. One 4-mg Ondansetron Hcl Tablet or one 4-mg Ondansetron Hcl Tablet or 5 mL (1 teaspoonful equivalent to 4 mg of ondansetron) of Ondansetron Hcl Oral Solution should be administered 3 times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.

Geriatric Use: The dosage is the same as for the general population.

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Dosage Adjustment for Patients With Impaired Renal Function: The dosage recommendation is the same as for the general population. There is no experience beyond first-day administration of ondansetron.
Dosage Adjustment for Patients With Impaired Hepatic Function: In patients with severe hepatic impairment (Child-Pugh2 score of 10 or greater), clearance is reduced and apparent volume of distribution is increased with a resultant increase in plasma half-life. In such patients, a total daily dose of 8 mg should not be exceeded.

SIDE EFFECTS

Headache, fever, lightheadedness, dizziness, drowsiness, tiredness, constipation, or redness/pain/burning at the injection site may occur. If these effects persist or worsen, notify your doctor promptly.Many people using this medication do not have serious side effects.Tell your doctor immediately if any of these unlikely but serious side effects occur: stomach pain, muscle stiffness/spasm, vision changes (e.g., temporary loss of vision, blurred vision, uncontrollable eye movements).Seek immediate medical attention if any of these rare but very serious side effects occur: chest pain, fainting, slow/fast/irregular heartbeat.A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

General: Flushing. Rare cases of hypersensitivity reactions, sometimes severe (e.g., anaphylaxis/anaphylactoid reactions, angioedema, bronchospasm, shortness of breath, hypotension, laryngeal edema, stridor) have also been reported. Laryngospasm, shock, and cardiopulmonary arrest have occurred during allergic reactions in patients receiving injectable ondansetron.

Hepatobiliary: Liver enzyme abnormalities
Lower Respiratory: Hiccups
Neurology: Oculogyric crisis, appearing alone, as well as with other dystonic reactions
Skin: Urticaria

PRECAUTIONS

Before using ondansetron, tell your doctor or pharmacist if you are allergic to it; or to other serotonin blockers or if you have any other allergies.
Before using this medication, tell your doctor or pharmacist your medical history, especially of: irregular heartbeat, liver disease, stomach/intestinal problems (e.g., recent abdominal surgery, ileus, swelling).
This drug may make you dizzy, drowsy, or cause blurred vision; use caution engaging in activities requiring alertness or clear vision such as driving or using machinery. Limit alcoholic beverages.
Infants younger than 5 months may be more sensitive to the effects of this drug, especially diarrhea.
During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

General: Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. The use of ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting may mask a progressive ileus and/or gastric distension.

INTERACTION

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with them first.

This drug should not be used with the following medication because a very serious interaction may occur: apomorphine.

If you are currently using the medication listed above, tell your doctor or pharmacist before starting ondansetron.Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/ herbal products you may use, especially: tramadol.
Other drugs besides ondansetron that may affect the heart rhythm (QTc prolongation in the EKG) include dofetilide, pimozide, procainamide, amiodarone, quinidine, sotalol, and erythromycin, among others. QTc prolongation can infrequently result in serious (rarely fatal) irregular heartbeat. Consult your doctor or pharmacist for more details and for instructions on how you may reduce your risk of this effect.

DRUG DESCRIPTION

The active ingredient inondansetron hydrochloride (HCl) as the dihydrate, the racemic form of ondansetron and a selective blocking agent of the serotonin 5-HT3 receptor type. Chemically it is (±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate.Ondansetron HCl dihydrate is a white to off-white powder that is soluble in water and normal saline. The active ingredient inOrally Disintegrating Tablets is ondansetron base, the racemic form of ondansetron, and a selective blocking agent of the serotonin 5-HT3 receptor type. Chemically it is (±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one.Each 4-mgTablet for oral administration contains 4 mg ondansetron base. Each 8-mgTablet for oral administration contains 8 mg ondansetron base.EachTablet also contains the inactive ingredients aspartame, gelatin, mannitol, methylparaben sodium, propylparaben sodium, and strawberry flavor.Tablets are a freeze-dried, orally administered formulation of ondansetron which rapidly disintegrates on the tongue and does not require water to aid dissolution or swallowing.

This medication is used alone or with other medications to prevent nausea and vomiting caused by cancer chemotherapy. It is also used to prevent and treat nausea and vomiting after surgery. It works by blocking one of the body's natural substances (serotonin) that causes vomiting.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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